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National Dairy Standard - GMP for Dairy

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Report Highlights:

On November 20, 2009, China notified the WTO of "National Food Safety Standard of the People's Republic of China for Good Manufacturing Practices for Dairy Products" as SPS/N/CHN/142. The date for submission of final comments to the WTO is January 1, 2010. The proposed date of entry into force has not been specified.

Executive Summary:

On November 20, 2009, China notified the WTO of "National Food Safety Standard of the People's Republic of China for Good Manufacturing Practices for Dairy Products" as SPS/N/CHN/142. The date for submission of final comments to the WTO is January 1, 2010. The proposed date of entry into force has not been specified.

According to the WTO notification, "This standard applies to manufacturing enterprises which use milk (or goat milk) and the processed products as the main raw material to process various types of dairy products. It specifies the site selection of dairy production enterprises and the factory

environment, plants and workshops, equipment, sanitary management, raw materials and packaging materials requirements, food safety control of production process, product testing, storage and transportation, records and documents management, product traceability and recall, training, management agencies, and personnel requirements for the dairy production enterprises.”

Thanks go to the consortium of industry and 3rd country Embassies in Beijing for their assistance in translating and reviewing this standard.

This report contains an UNOFFICIAL translation of National Standard on Good Manufacturing Practice for Dairy.

General Information:

BEGIN TRANSLATION

ICS 67.040

GB National Food Safety Standard
GB ××××—××××
In substitution of GB 12693-2003

Good Manufacturing Practices for Dairy Products

Issued on xx-xx-xxxx

Implemented on xx-xx-xxxx

Issued by the Ministry of Health
of the People’s Republic of China

Preface

The Standard is in substitution of GB 12693—2003 Good Manufacturing Practice of Dairy Product Factory and GB21692—2008 Hygienic Practice for Dry Milk Powder.

The Standard corresponds to Codex Alimentarius Commission (CAC) CAC/RCP1-1969, Rev.4-2003 General Principles for Food Hygiene and CAC/RCP57-2004 Code of Hygienic Practice for Milk and Milk Products as well as makes reference to EU Regulations (EC) No 853/2004 Regulation on the Hygiene of Foodstuffs and (EC) No 853/2004 Specific Hygiene Rules for Food of Animal Origin. The consistence of the Standard with CAC/RCP1-1969, Rev.4-2003 and CAC/RCP 57-2004 is non-equivalent.

As compared to GB12693-2003, the Standard has made the following amendments:

- Adjustment to the application scope, stressing the contamination prevention in the whole production process of incoming of raw materials, food safety control of production process, product transportation and storage;

- Emphasizing the application to production enterprises of different dairy products;
- Adjusting “Production Equipment”, setting out requirements for layout, material quality and design of production equipment in view of preventing microbial, chemical and physical contamination;
- Canceling the hardware requirement in construction of laboratories;
- Adding requirements relating to the purchase, acceptance, transportation and storage of raw materials;
- Emphasizing the food safety control in production, and formulate the major measures for control of microbial, chemical and physical contamination;
- Adding packing materials and use requirement;
- Adding requirements for control index, monitoring and recording of key control points;
- Adding particular requirements for follow-up and call-back of products; and
- Adding file management requirements of records.

The Standard is put forward by and in convergence case-management of the Ministry of Health of the People’s Republic of China.

Publication status of previous versions substituted by the Standard is as follows:

- GB 12693-1990, GB12693-2003. GB ××××-××××

Good Manufacturing Practices for Dairy Product Factories

1 Scope

The Standard specifies the requirements for location of dairy product factories and plant environment, plant and workshop, equipment, hygiene management, raw materials and packing materials and the requirements for food safety control in production, product testing, product storage and transportation, record and document management, product follow-up and call-back, management organization and personnel.

The Standard applies to production enterprises processing different dairy products with cow milk (or goat milk) and their processed products as the main raw materials.

2 Cited Normative Documents

The provisions of the following documents become the provisions of the Standard upon citation hereto. Where the cited documents are dated, none of their subsequent amendments (exclusive of corrections) or revisions shall be applicable to the Standard. However, the parties concluding any agreement in accordance with the Standard are encouraged to study if to use the latest versions of such documents. Where the cited documents are not dated, their latest versions shall be applicable to the Standard.

GB 5749 Hygienic Standard for Drinking Water

GB 8978 Integrated Sewage Discharge Standard

GB 14881 General Hygienic Practices for Foodstuff Enterprises

3 Terms and Definitions

The following terms and definition are applicable to the Standard.

3.1 Clean Work Area

Work area with high requirement for cleanness, such as storage area for exposed semi-finished products, filling room and inner packing area, etc.

3.2 Quasi-clean Work Area

Work area with requirement for cleanness following that of cleaning work area, such as pretreatment workshops of raw materials, etc.

3.3 Common Work Area

Work area with requirement for cleanness following the quasi-clean work area, such as milk collection unit, raw material warehouse, packing material warehouse, outer packing workshop and finished-product warehouse, etc

4 Location and Plant Environment

4.1 Location

4.1.1 Plant site shall be located far away from the toxic and hazardous areas and other sources of contamination; no dust, harmful gas, radioactive substance and other diffusive contamination sources shall be allowed around the plant; no contaminable conditions such as potential areas for massive population of insects shall be allowed.

4.1.2 The plant site shall not be located downstream of any contaminated river, but shall be located in the area with convenient communications and an adequate water source.

4.2 Plant Environment

4.2.1 The plant site shall be rationally laid out, with clear-cut functional areas and isolation measures; such facilities causing contamination as boiler room shall be located at the down-wind side with the wind direction of maximum annual frequency; incinerator, boiler, sewage treatment station and pollutants disposal yard shall have certain distance away from the production workshop, warehouse and water supply facility as well as protective measures.

4.2.2 Within the plant site, the open area and road shall be paved with concrete, asphalt or other hard materials or shall be afforested, to keep the environment clean and prevent any dust and water from flying and gathering.

4.2.3 Animal feeding is prohibited within the plant area.

4.2.4 The plant area shall be fenced with proper devices to govern the external contamination source and invasion of hazardous animals.

5 Plant and Workshop

5.1 Design and Layout

5.1.1 Any construction, expansion and reconstruction project shall be designed and executed according to the relevant national regulations.

5.1.2 Plant and workshop shall be laid out to prevent any cross contamination in the process of dairy product processing and avoid any contact with any toxic and unclean substances.

5.2 Area Division and Isolation

5.2.1 Area division shall be laid out in an orderly way, based on the results of risk assessment, according to the needs of production techniques and hygienic requirements.

5.2.2 Workshop should be isolated inside according to the requirement for cleanness of work area and production needs to prevent any cross contamination.

5.3 Internal Building Structure

5.3.1 Roof

5.3.1.1 Interior roof of such areas as processing, packing and storing should be easily cleaned to prevent dust from accumulating and avoid such circumstances as condensation, fungi-growth or falling. Where the roof of clean work area, quasi clean work area and other arenas of foodstuff exposure (except for milk collect house) is of the structure that can easily become dirty, it is better to install the level and smooth and easy-to-clean ceiling; in case of the reinforced concrete structure, the interior roof should be even and seamless, while the top angle should have a proper radius.

5.3.1.2 The interior flat roof or ceiling of workshop should be built with non-toxic and odorless white or light-color waterproof materials. Where the paint coating and spraying is required, it is necessary to use the mould-proof paint that will not come off and can be easily cleaned.

5.3.1.3 Pipelines of steam, water and electricity shall not be arranged right above the food exposure; otherwise, facilities shall be installed to prevent dust and condensed water from falling down.

5.3.2 Walls

5.3.2.1 Walls should be constructed with non-toxic, odorless, smooth, water-proof and easy-to-clean light-color anti-corrosion materials.

5.3.2.2 The wall corners and pillar corners (between walls, between wall and pillar and between call and pillar and ceiling) in the clean work area and quasi clean work area shall maintain certain radian for the convenience of washing clean and sterilizing.

5.3.2.3 The wall surface within the operating height shall be smooth.

5.3.3 Doors and windows

5.3.3.1 Smooth and anti-absorption materials shall be used, which should be easily washed clean and sterilized.

5.3.3.2 For the production workshop and storage arenas, doors and windows shall be tightly installed and the stainless screen windows and nets can be arranged, which can be easily removed for washing clean; it is better not to install any windowsill for windows; in case of any windowsill, it should be more than 1m above the ground and should be tilted inward with certain angle for the convenience of cleaning.

5.3.3.3 The exits of the clean work area and quasi clean work area should be installed with doors that can be automatically closed (such as with auto inductor or door closer) and/or air curtain.

5.3.4 Flooring

5.3.4.1 The floor should be made with non-toxic, odorless and impervious materials and shall be even and non-slippery, seamless and easy for cleaning and sterilizing.

5.3.4.2 The floor in the areas with drainage or waste water flowing to the floor in operation, frequently wet work environment or cleaning by washing with water should be also anti-acid and anti-alkali, and should have certain drainage slope and drainage system.

5.4 Facilities

5.4.1 Water supply facilities

5.4.1.1 Able to secure the water quality, pressure and volume required for production.

5.4.1.2 Water storage tank (tower and sink), water pipeline and apparatus in direct contact with water should be made with non-toxic, odorless and anti-corrosion materials. It is necessary to regularly clean and sterilize the water tank (tower and sink) and regularly check the water quality and define the cleaning and sterilizing schedule according to the status of water quality inspection so as to ensure the conformity of production water quality with the provisions of GB 5749.

5.4.1.3 The inlet and outlet of water supply facilities should be equipped with safety and hygiene devices to prevent any harmful animal and other hazardous substances from entering, resulting in contamination to foodstuffs.

5.4.1.4 The standby water supply should be located at least 30m away from any contamination source (such as septic tank, refuse storing yard, etc)³ and should be provided with hygienic protection belt and taken care of by specific persons.

5.4.1.5 To use the standby water sources, it is necessary to install the relevant water purification devices (such as sediment, filter, iron removal, manganese removal, fluoride removal, sterilization, etc) according to the features of local water quality, to ensure the conformity of water quality with the provisions of GB 5749.

5.4.1.6 The piping system for non-drinking water not in contact with foodstuffs (such as cooling water, sewage or waste water, etc) should be clearly divided from the piping system for foodstuff production water, and such water shall be delivered with separate pipelines without any backflow or intersection.

5.4.2 Drainage system

5.4.2.1 It is necessary to allocate the proper drainage system, and avoid, in designing and constructing, products or production water from being contaminated.

5.4.2.2 The drainage system should have a slope and remain unobstructed and convenient for washing; the juncture of sides and bottom of the drainage ditch should have certain radius, while the curve radius shall be at least 3cm.

5.4.2.3 At the inlet of the drainage system, a floor drain with water stop should be installed to prevent any solid waste from flowing in and foul smell from coming out.

5.4.2.4 No other pipelines shall be arranged inside and below the drainage system.

5.4.2.5 The drainage outlet shall be equipped with a device to prevent the invasion of any harmful animal.

5.4.2.6 The flow direction of indoor drainage should be from the area with higher requirement of cleanness to the area with lower requirement of cleanness, and should be designed to prevent the backflow of waste water.

5.4.2.7 Waste water shall be discharged into the waste water treatment system or disposed in other proper ways.

5.4.3 Cleaning facilities

Proper facilities should be allocated for foodstuffs, apparatus and equipment cleaning and for storage of refuse and waste materials.

5.4.4 Personal hygienic facilities

Such personal hygienic facilities as hand washing, sterilizing and locker room should be allocated, which shall comply with the provisions of GB14881.

5.4.5 Ventilation facilities

5.4.5.1 Measures of natural ventilation or artificial ventilation should be made available to reduce the atmospheric contamination and control odor so as to secure the food safety and product characteristics. For production of milk powder, the ambient temperature should be also controlled in the clean work area and so is the atmospheric humidity when it is necessary.

5.4.5.2 The clean work area shall be installed with air conditioning facilities to prevent excessively high interior temperature and condensation of steam and keep the interior air fresh; the common work area shall be installed with ventilation facilities to promptly exhaust humid and dirty air. In case of air conditioning, ventilation and exhausting or fan application inside the plant, the air flow direction should be from the area of higher cleanness to the area of lower cleanness to prevent any foodstuff, production equipment and inner packing materials from being contaminated.

5.4.5.3 In the area with odor and gas (steam and toxic and harmful gas) or dust that may contaminate foodstuffs, proper elimination, collection and control devices shall be allocated.

5.4.5.4 Air outlets should be equipped with the corrosion-resistant screen covers that can be easily cleaned to prevent the invasion of any harmful animal; the air inlet should be at least 2m above the floor, far away from the contamination source and air outlet and provided with air filters. The ventilating and exhausting devices should be easily removed for cleaning, maintenance or replacement.

5.4.5.5 The compressed air or other gas used for foodstuffs, clean food contact face or equipment shall be filtered and purified to prevent any indirect contamination.

5.4.6 Lighting facilities

5.4.6.1 Plant should have adequate natural lighting or artificial lighting inside. The lighting coefficient for the workshop shall not be lower than Standard IV; the mixed illumination shall not be lower than 540 lx for the work area of quality monitoring and control, not less than 220 lx for the work area of processing, and not less than 110 lx for other areas, except for the areas sensitive to light. The light source shall not cause any change in the color of foodstuffs.

5.4.6.2 The lighting facilities shall not be installed right above the foodstuff exposure; otherwise, safe lighting facilities shall be used to prevent any break and contamination of foodstuff.

5.4.7 Storing facilities

5.4.7.1 Enterprises shall have storing facilities meeting the types and quantity of dairy products produced and operated.

5.4.7.2 Separate storage areas should be arranged according to different natures of raw materials, semi-finished products, finished products and packing materials and, when necessary, freezing (cooling) storages should be arranged. To store goods of different nature in one warehouse, it is necessary to apply proper isolation (e.g., by classification, rack and division).

5.4.7.3 Warehouses shall be built with non-toxic, solid materials and the floor shall be level and even for ventilation and should be provided with devices to prevent the invasion of any harmful animal (such as rat guard or ditch set up at the entrance of the warehouse).

5.4.7.4 Warehouses should be arranged with adequate stack board (for placing goods) and keep

the stored goods appropriately away from the walls and which should be kept away from the walls and floor for the benefit of air circulation and goods handling.

5.4.7.5 Cooling (cold) stores should be equipped with the thermostat, temperature measuring device or temperature auto recording meter that can accurately indicate the temperature inside the warehouse and carry out the real-time control of temperature.

6 Equipment

6.1 Production equipment

6.1.1 General requirements

6.1.1.1 Adequate production and operation equipments should be arranged in compliance with the types and quantity of dairy products produced and operated, of which the capacity can cooperate with each other.

6.1.1.2 All the production equipments shall be orderly arranged as per technical procedures to ensure the smooth production and avoid any cross contamination.

6.1.1.3 For the special equipments used in production such as pressure vessel and pressure pipeline, it is necessary to formulate the relevant operating rules.

6.1.2 Material quality

6.1.2.1 All the equipments and instruments in direct or indirect contact with raw materials, semi-finished products and finished products shall be made with safe, non-toxic, smell-free or odorless, non-absorptive and corrosion-resistant materials that can bear the repeated cleaning and sterilizing. Additionally, it is necessary to avoid using any improper materials that may cause contact corrosion.

6.1.2.2 The contact surface with products shall not be of wood materials or any material that cannot be adequately washed clean and sterilized.

6.1.3 Design

6.1.3.1 All the machinery and equipments shall be designed and constructed for the convenience of cleaning and sterilizing and the easiness of checking. They should have such construction as to avoid, in use, entrance of any lubricant, metal slag, sewage or other substance that may cause contamination into foodstuff and shall comply with the relevant requirements.

6.1.3.2 The contact surface with foodstuff shall be smooth and even, without any sag or crack to reduce the accumulation of foodstuff debris, dirt and organic matters.

6.1.3.3 The storage, transportation and processing system (including the gravity, pneumatic, enclosure and automation system) should be designed and manufactured to the convenience to keep it in a good hygienic state.

6.1.3.4 In the areas of food processing or handling, the equipments and instruments not in contact with foodstuff shall have a construction for easy maintenance in a clean state.

6.1.3.5 All the goods and materials storing equipments in the plant shall be provided with the top covers. Outside the production areas and the storing areas for raw materials and packing material, there shall be the racks designated for storing the spare components of equipment, which can be easily kept clean and dry to ensure the timely return of different tools to the designated places after use.

6.2 Monitoring Equipment

6.2.1 Such monitoring equipments for measuring, controlling and recording as pressure gauge and thermostat should be accurate and effective; where mandatory calibration is required, calibration shall be carried out in accordance with relevant regulations; where mandatory calibration is not required, enterprises should carry out the correction according to the user's instructions.

6.2.2 In using a computer system and the network technology thereof for collection of monitoring data at the key control points and for management of different records, the relevant functions of the computer system and the network technology thereof may be referred to the provisions of Addendum A to the Standard (Referential Addendum).

6.3 Service and Maintenance of Equipment

6.3.1 It is necessary to establish and strictly execute the equipment service and maintenance procedures.

6.3.2 It is necessary to establish the daily maintenance and service schedule for equipment and carry out regular overhaul and keep proper records.

6.3.3 Before production each time, it is necessary to check if the equipment is in a normal state to avoid any impact on the hygienic quality of products; in case of any fault, it is necessary to promptly eliminate it and record the faulting time, reason and batches of products that may be affected.

7 Hygiene Management

7.1 Hygiene Management System

7.1.1 Enterprise shall formulate the hygiene management system and examination standards and implement the post responsibility system.

7.1.2 Enterprise shall formulate the hygiene inspection schedule and record and file the execution of such schedule.

7.2 Hygiene Management for Plant and Facilities

7.2.1 All facilities inside the plant shall be kept clean and promptly maintained and replaced; in case of any damage to the plant roof, ceiling and walls, repair shall be immediately carried, while the floor shall not be allowed to have any damage or water logging.

7.2.2 Equipment and tools and instruments for processing, packing, storing and transporting, production pipelines and contact surface with foodstuffs shall be regularly cleaned and sterilized. In cleaning and sterilizing, make sure to prevent any contamination to foodstuffs, contact surface with foodstuff and inner packing materials.

7.2.3 The cleaned and sterilized movable equipment and instruments shall be kept in a place that can prevent their contact surface with foodstuffs from being contaminated again and keep them in an applicable state.

7.3 Cleaning and Sterilizing

7.3.1 It is necessary to formulate the effective plan and procedure for cleaning and sterilizing to ensure the clean and hygienic state of foodstuff processing arenas, equipment and facilities and prevent any contamination of foodstuffs.

7.3.2 Enterprises may choose the cleaning and sterilizing methods according to the features of products and process.

7.3.3 Equipment and instruments used for cleaning and sterilizing shall be kept properly in a special place.

7.3.4 It is necessary to record the cleaning and sterilizing procedures, such as the type of detergent and sterilizer, time, density, object, temperature, etc.

7.4 Human Health and Hygiene Requirements

7.4.1 Human health

7.4.1.1 Enterprises shall establish and execute the employees' health management system.

7.4.1.2 Foodstuff production and operation personnel shall annually undertake the health check and obtain the health certificate before being put into work.

7.4.1.3 Persons suffering from such notifiable diseases as dysentery, typhoid and viral hepatitis, persons suffering such diseases impacting the food safety as active pulmonary tuberculosis, suppurative or effusive skin diseases and persons with skin injuries shall be no longer allowed to undertake any work in direct contact with dairy products.

7.4.2 Personal hygiene

7.4.2.1 Dairy product processing personnel shall maintain excellent personal hygiene.

7.4.2.2 Before entering the production workshop, it is a must to wear or put on the clean work uniform, cap and shoes or boots. The work uniform should cover the overcoat; hair should not come from the cap and when necessary, mask should be put on. Entering the toilet or leaving the production and processing arenas with the work uniform, shoes and boots on are not allowed.

7.4.2.3 Before being posted, for instance after going to the toilet, contacting any goods that may contaminate the foodstuffs or undertaking any other activities not related to production, it is necessary to wash hands and apply sterilization. The hands shall be kept clean in the process of operating.

7.4.2.4 Persons in direct contact with dairy product shall not use any nail oil and perfume and shall not wear watch and jewelries.

7.4.2.6 At work, smoking, taking food or other activities that may impact the hygiene of dairy products shall not be allowed.

7.4.2.7 Personal clothes shall be kept in the lockers in the locker room and other personal belongings shall not be allowed for carrying in the production workshop.

7.4.3 Visitors

To enter the foodstuff production, processing and operating arenas, visitor shall comply with the hygienic requirements for the operating personnel on the spot.

7.5 Pest Control

7.5.1 Formulate measures for pest control to avoid the population of pests.

7.5.2 Keep the environment neat and clean and buildings intact to prevent the invasion of pests and development of harmful animals.

7.5.3 At the production workshop and storage arenas, set up the pest-capture lights to prevent or eliminate the harmful pests.

7.5.4 Regularly monitor and check if the plant environment and production arenas have any sign of pests; in case of observing any pest, trace and find out the source and stop its occurrence again.

7.5.5 Physical, chemical or biological preparation may be used for treatment, but their eliminating

method shall not impact the safety and characteristics of foodstuffs and contaminate the contact surface with foodstuffs and packing materials (e.g., avoid using insecticide).

7.6 Disposal of Refuses

7.6.1 Formulate rules for placing and eliminating refuses.

7.6.2 The vessels containing the refuses, processing by-products and non-edible or dangerous substances shall have special labels and rational construction, and, when it is necessary, shall be closed to prevent any contamination to the foodstuffs.

7.6.3 It is necessary to set up the temporary dumping facilities a proper location for classified dumping as per characteristics of refuses, while the corruptive refuses should be regularly eliminated.

7.6.4 The dumping place of refuses shall not produce any bad smell or harmful, toxic gas. It is necessary to prevent the population of harmful animals and prevent any contamination to the foodstuffs, contact surface with foodstuff, water source and ground.

7.7 Management of Toxic and Harmful Substances

Management of toxic and harmful substances shall be subject to the relevant provisions of GB 14881.

7.8 Management of Sewage and Filth

7.8.1 Sewage discharge shall be compliant with the requirements of GB 8978 and those failing to comply with the standard shall be purified for qualification before being discharged.

7.8.2 Management of filth shall be subject to the relevant provisions of GB 14881.

7.9 Management of Work Uniforms

Management of work uniforms shall be subject to the relevant provisions of GB 14881.

8 Requirements for Raw Materials and Packing Materials

8.1 General Requirements

8.1.1 Production enterprises of dairy products shall establish the management system relating to the purchase, acceptance, transportation and storage of raw materials and packing materials so as to ensure the raw materials and packing materials used are in conformity with the requirements of the laws and regulations.

8.1.2 Fresh milk collection centers constructed by production enterprises of dairy products shall comply with the relevant national and local regulations.

8.2 Requirements for Purchase and Acceptance of Raw Materials and Packing Materials

8.2.1 Production enterprises of dairy products shall establish the supplier management system, specifying the procedures for supplier selection, examination and appraisal.

8.2.2 Production enterprises of dairy products shall establish the incoming inspection system for raw materials and packing materials.

8.2.2.1 Production enterprises of dairy products with fresh milk shall test, batch by batch, the fresh milk acquired, record truly the quality inspection status, suppliers' names and contact modes, delivery date, etc, and check the fresh milk receipts of the transporting vehicles. Production enterprises of dairy products shall not be allowed to purchase any fresh milk from any unit and individual without the license of fresh milk acquisition.

8.2.2.2 In inspecting and accepting other raw materials and packing materials, it is necessary to check the qualification certification documents (enterprise's self-examination report or testing report issued by a third party) for the batch of raw materials and packing materials; in case of failing to provide such effective qualification certification documents, according to the relevant food safety standards or the enterprise's inspection and acceptance standard, inspect and test the raw materials and packing materials purchased, which shall be only accepted and used upon qualification. It is necessary to record truly the relevant information of raw materials and packing materials.

8.2.3 Raw materials and packing materials that are refused for acceptance upon determination shall be demarcated and separately stored and the supplier shall be notified for further action.

8.3 Transportation and Storage of Raw Materials and Packing Materials

8.3.1 Production enterprises of dairy products shall transport and store raw materials and packing materials according to the requirements of ensuring the quality and safety of raw materials and packing materials.

8.3.2 Transportation and storage of fresh milk

8.3.2.1 The vessels for transporting and storing fresh milk shall comply with the relevant national safety standard.

8.3.2.2 Fresh milk shall be, within 2 hours after milking, cooled down to 0°C~4°C, at which it shall be transported. The transporting vehicles shall maintain perfect certificate and record.

8.3.2.3 Upon delivery to the factory, the fresh milk shall be promptly processed or shall be stored cold at a temperature of 2°C-6°C, in the event that it cannot be timely processed.

8.3.3 Transportation and storage of other raw materials and packing materials

8.3.3.1 In the process of transporting and storing raw materials and packing materials, avoid any direct sunlight, rain, sharp temperature and humidity change and impact. Loading and shipping with toxic and harmful goods is prohibited.

8.3.3.2 In the process of transporting and storing, avoid any contamination and damage and minimize the poor quality; the raw materials and packing materials with requirement for humidity and temperature and special requirements shall be transported and stored according to the specified conditions.

8.3.3.3 During the storage, according to their respective features, different raw materials and packing materials shall be divided for storage, for which the identification should be set up to indicate the relevant information and quality status.

8.3.3.4 Regularly check the stocked raw materials and packing materials; as for the raw materials and packing materials that have been stored for a longer period and may have observe any change in quality, regularly undertake sampling for confirmation of quality and timely dispose the raw materials and packing materials that have been deteriorated or exceeded the warranty period.

8.3.4 In using the qualified raw materials and packing materials, follow the principle of "early expiration date and first out" for rational arrangement of use.

8.4 Maintain the Records on Purchase, Acceptance, Storage, Transportation and Use of Raw Materials and Packing Materials.

9. Food Safety Control in Production

9.1 General Requirements

Production enterprises of dairy products shall formulate the management measures of controlling food hazards, which shall include:

9.1.1 Identify the contamination source, channel and relevant factors, causing contamination in production;

9.1.2 Determine the relevant control links and implement the effective control measures;

9.1.3 Monitor the control measures and ensure their effectiveness;

9.1.4 Examine and review the control measures regularly and in case of any change in operating.

9.2 Key Factors for Food Safety Control

9.2.1 Control of microbial contamination

9.2.1.1 Temperature and time

a) Enterprises shall specify, according to the features of products, the method for eliminating or constraining the growth and development of microbes, such as thermal treatment, freezing or cold storage and implement the effective monitoring and control.

b) Enterprises shall establish the measures for temperature and time control and rectification and carry out the regular verification.

c) As for the processing links with strict control over temperature and time, establish the real-time monitoring measures and maintain the monitoring and control records.

9.2.1.2 Humidity

a) Enterprises shall control, according to the features of productions and techniques, the atmospheric humidity in the areas requiring for humidity control so as to reduce the development of harmful microbes; formulate and effectively implement the key limits of atmospheric humidity.

b) Establish the real-time control and monitoring measures for atmospheric humidity, regularly verify the same and keep records.

9.2.1.3 Atmospheric cleanness in production area

Production workshop shall be kept with clean air to prevent the contamination to foodstuffs. For instance, determine as per natural settlement method specified in GB/T 18204.1. The colony count in the air of the clean work area shall be controlled with 30cfu/dish.

9.2.1.4 Prevention against microbial contamination

a) Production enterprises of dairy products shall take necessary measures for the whole process from intake of raw materials and packing materials to dispatch of finished products to prevent any microbial contamination.

b) In operating, using and maintain any equipment, vessel and instrument used for conveying, loading or storing raw materials, semi-finished products and finished products, avoid any contamination to the foodstuffs in processing or storing.

c) For ice lumps and steam in direct contact with foodstuffs in processing, water used shall comply with the provisions of GB 5749.

d) Recycling water shall be treated and it should be ensured that it will cause any hazard to the safety of foodstuffs and characteristics of products. Water treatment shall be effectively monitored. The recycling water without further treatment and the recycled water for evaporation or drying in processing foodstuff can be reused, but it must be ensured that it will not result in

any hazard to the safety of foodstuffs and characteristics of products.

9.2.2 Control of chemical contamination

9.2.2.1 Enterprise shall establish the management system to prevent chemical contamination, analyze the possible contamination source and contamination channel, and set forth the control measures;

9.2.2.2 Detergent, sterilizer, insecticide and lubricant in compliance with the requirement should be selected and used as pre requirement of the product instructions; should be stored separately from the foodstuffs and demarcated clearly; taken care of by specific persons. Their use shall be registered and application records should be properly kept to avoid any hazard of contaminating the foodstuffs.

9.2.3 Control of physical contamination

9.2.3.1 Production enterprises of dairy products shall undertake such measures as equipment maintenance, hygiene management, spot management, management of external persons and processing supervision to ensure that products will not be contaminated by the foreign stuffs (such as glass or metal fragments, dust, etc).

9.2.3.2 Take effective measures (such as sieve, trap, magnet, electronic metal detector, etc) to prevent any metal or other foreign stuffs from being mixed into the products.

9.2.3.3 During production, such work as welding, cutting and grinding shall not be carried to avoid any contamination of odor and fragment

9.2.4 Food additives

9.2.4.1 Enterprises shall use the food additives according to the provisions of the Food Safety Standard on types, application and dosage of food additives.

9.2.4.2 In using, weigh and measure accurately the food additives and maintain proper records.

9.2.5 Packing materials

9.2.5.1 Packing materials should be clean, non-toxic and compliant with the national relevant regulations.

9.2.5.2 Packing materials or gas for packing must be non-toxic, and shall not affect the safety of foodstuffs and characteristics of products under the specific conditions of storing and using.

9.2.5.3 The inner packing materials should be able to adequately protect, in the normal storage, shipment and sale, foodstuffs against any contamination, prevent any damage and avoid any harmful substance from entering the foodstuffs.

9.2.5.4 The recyclable packing materials such as glass bottles and stainless vessels should be washed clean and sterilized before being used.

9.2.5.5 Before packing, it is necessary to check the labels of the packing materials to be used, avoid any misuse of packing materials, and keep a record, including the product name, quantity, operator and date.

10 Testing of Products

10.1 Enterprises shall test each batch of products according to the relevant standard and retain the samples; dispatch only the qualified products.

10.2 Enterprises may carry out such test independently or entrust any testing organization

qualified for foodstuff testing to carry out such test.

10.3 Testing method shall be subject to the national standard method; where any other method than the national standard method is used, it is necessary to regularly check it with the standard method.

10.4 Enterprises shall file complete testing records and reports.

11 Product Storage and Transportation

11.1 According to the types and nature of products, select the mode of storage and transportation, which shall be in conformity with the special requirements such as temperature to ensure the safety of dairy products.

11.2 In the process of storage and transportation, avoid any direct sunlight, rain, sharp temperature and humidity change and impact to avoid any bad impact on the composition, content, and quality of dairy products. Loading and shipping with toxic and harmful goods is prohibited.

11.3 The vessels, tools and equipment used for storing, transporting and handling shall be clean and safe and in an excellent state of renovation and service to prevent the products from contamination.

11.4 Regularly check the products stocked in warehouses, and, if necessary, maintain the record of temperature and/or humidity; in case of anything abnormal observed, take prompt action.

11.5 As for the tested products, indicate their quality status; disqualified products shall be separately stored, explicitly demarcated and timely disposed; disqualified products shall not be dispatched.

11.6 The storage and transportation of products shall be recorded and the dispatched products shall be also recorded so that they can be promptly called back in case of any problem observed.

12 Management of Records and Documents

12.1 Records and Management

12.1.1 Enterprises shall establish the relevant record management system and keep detailed records of the purchase, production, storage, testing and sales of raw materials and packing materials in dairy product processing so as to increase the reliability and effectiveness of the food safety management system.

12.1.1.1 Enterprises shall establish the inbound test record system for food raw materials, foodstuff additives and food-related product to truly record the names, specifications, quantity, supplier's name and contact mode and intake date of food raw materials, food additives and food-related products.

12.1.1.2 Enterprises shall establish the record system of food processing, storing and testing to truly record the product processing, product storing and products' testing batch number, testing date, inspectors, test results, etc.

12.1.1.3 Enterprises shall establish the record system of foodstuff ex-factory test, check the testing record and safety status of dispatched food, and truly record foodstuffs' names, specification, quantity, production date, production batch number, place of delivery, receiver's

name and contact mode and date of dispatch.

12.1.1.4 Enterprises shall establish the food call-back record system to truly record the called-back foodstuff's name, batch number, specification, quantity, reason for call-back and subsequent rectification program.

12.1.2 All records shall be checked and signed or stamped by the execution personnel and relevant supervisor; in case of any modification in the record, the original text shall not be crossed out, resulting in the failure to identify the original text, and upon modification, the modifier shall sign or stamp by the modified text.

12.1.3 All the production and quality management records shall be reviewed by the relevant department to determine if all the treatment is conformity with the regulations; in case of anything abnormal observed, immediate action shall be taken.

12.1.4 Enterprise shall maintain the relevant records specified hereto for at least two years.

12.2 Document Management

12.2.1 Enterprises shall establish the document management system and set up complete quality management files; documents shall be filed and kept as per classification. Documents to be distributed and used shall be the approved prevailing version. The abandoned or invalid documents shall not appear in the work area except for filing and reference.

12.2.2 Enterprises are encouraged to use advanced technical means (such as electronic computer information system) for management of documents and records.

13 Product Follow-up and Call-back

13.1 Enterprises shall establish the product tracing system and maintain the relevant records of all the links ranging from purchase of raw materials to sale of products so as to ensure the effectiveness of the whole product tracing and call-back system.

13.2 Enterprises shall establish the product call-back system. Upon observing one batch or type of products contains or may contain any factor harming the health of consumers, it is necessary to actuate the product call-back procedure as per national relevant regulation, promptly notify the relevant department and keep proper record.

13.3 Foodstuff producers shall take action against the called-back foodstuffs such as rectification, harmless treatment and destruction and report to the relevant department about call-back and disposal status of the foodstuffs.

13.4 It is necessary to establish the processing mechanism for customer complaint. As for the written or oral views and complaints of customers, enterprises' relevant management department shall keep a record and find out the reason for proper processing.

14 Training

14.1 Enterprises should establish the training system for food safety knowledge training of all their employees.

14.2 Enterprises should formulate the annual training program according to different jobs for relevant training and certificates shall be required for the specific jobs.

14.3 It is necessary to regularly examine and revise the training program, evaluate the training

effect and carry out routine inspection so as to ensure the effective implementation of the program.

14.4 Training should be recorded.

15 Management Organization and Personnel

15.1 Enterprises shall establish and perfect their respective food safety management system, undertake relevant management measures to implement the total quality and safety control over the production of dairy product including the input of raw materials and output of finished products and ensure the products are in conformity with the requirements of the laws, regulations and relevant standards.

15.2 Establish the administration of food safety to take on the enterprise's food safety management and promote the continual improvement. The administration should include such relevant sectors as production, quality control and equipment.

15.3 Administration of food safety and relevant departments shall have a responsible person each. The responsible person of the administration shall be the executive of the enterprise and all the responsible persons shall have certain education background and management experiences.

15.4 All the departments of the administration shall have the relevant management duties. The production department is responsible for the quality of product processing and products and ensure the posted employees will operate as per job practice regulations of the enterprise; quality management department shall be responsible for raw materials and packing materials, production quality control, and testing of finished products, control and manage all the links relating to the food safety and take on the release of raw materials and packing materials, semi-finished products and finished products; equipment management department shall carry out the maintenance and service of routine production equipment and facilities relating to the product quality and ensure the normal operation of equipment and facilities.

15.5 All the concerned departments shall be effectively allocated with tasks, formulate the relevant management rules for the plant's internal and external environment, maintenance and management of plant facilities and equipment, production quality and safety management, hygiene management, quality tracing, etc, and define the management executive and duties.

15.6 All the departments of the food safety administration shall be allocated with fulltime or part-time food safety management personnel especially trained to propagate and carry out the regulations of food safety and relevant rules and regulations and take on supervising and the execution and keeping the relevant records.